K081151

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510(k) Summary

SEP - 8 2008

Safety and effectiveness information concerning this device is summarized below. Because this is not a Class III device, the special certification defined in this section is not required.

Submitted by:

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Date Prepared: 25 Feb 2008

Proprietary Name: Neuvo

Common Name: Electroencephalograph (EEG)

Classification Name: GWQ, GWP, GWF, GWE, GWJ

Device Classification: Class II: 21 CFR § 882.1400 Electroencephalograph

Predicate Device: SynAmps2
510(k) # K023771

Description of the Device:

The Compumedics Neuvo System is intended for measuring recording of the electrical activity of a patient's brain and/or through the attachment of multiple electrodes at various locations to aid in monitoring and diagnosis as routinely found in clinical settings for EEG. The system is intended for the EEG and long/middle/short-latency EP registration in the research environment. The system is intended to be used by qualified/trained EEG technologists and/or physicians. The data acquired must be interpreted by a qualified physician.

The Neuvo Amplifier System is an EEG/ERP/EP amplifier and data acquisition system. The amplifier and data acquisition electronics are housed in a small enclosure (Headbox) placed near the patient, and into which individual electrodes, collections of electrodes, may be connected. Additionally a high density electrode cap connector is provided on the Headbox. The Headbox also contains a connector for the interconnect cable to the System Unit.

The System Unit is slightly larger than the Headbox and serves as an interface between up to four Headboxes and the host computer.

The system operates under the software control of a host computer over an Ethernet 100BaseT interface. Data flows from the Neuvo amplifier over this interface.

NEUVO SYSTEM COMPONENTS

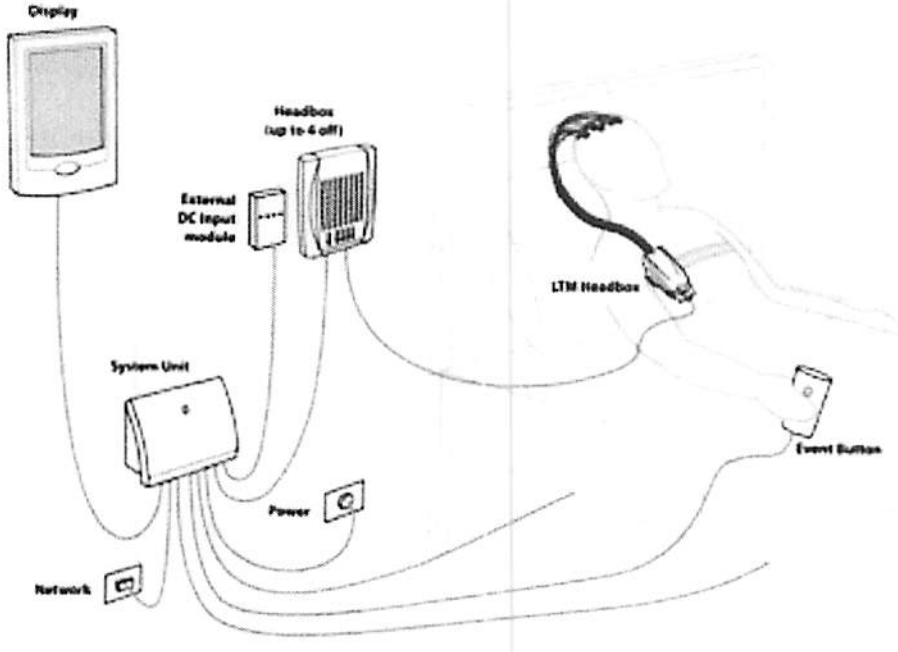

Figure 1-1 Illustration of the various Neuvo components.

Figure 1-1 illustrates the various components that can be used in a Neuvo system. Note that the cable management system is not shown.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Compumedics USA, Limited
c/o Intertek Testing Services
Mr. Daniel W. Lehtonen
2307 East Aurora Road, Unit B
Twinsburg, Ohio 44087

APR - 9 2012

Re: K081151
Trade/Device Name: Compumedics Neuvo
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: GWQ, GWF, GWJ, GWE
Dated (Date on orig SE ltr): August 22, 2008
Received (Date on orig SE ltr): August 25, 2008

Dear Mr. Lehtonen:

This letter corrects our substantially equivalent letter of September 8, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2 - Statement of Indications for use

Applicant: Compumedics USA, Ltd

510(K) Number: K081151

Device Name: Compumedics Neuvo

Indications For Use: The Compumedics Neuvo System is intended for measuring recording of the electrical activity of a patient's brain and/or through the attachment of multiple electrodes at various locations to aid in monitoring and diagnosis as routinely found in clinical settings for EEG. The system is intended for the EEG and long/middle/short-latency EP registration in the research environment. The system is intended to be used by qualified/trained EEG technologists and/or physicians. The data acquired must be interpreted by a qualified physician.

Presscription Use ✓ AND/OR Over the Counter Use_____
(Per 21 CFR 801 SubpartD) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of device Evaluation (ODE)

K081151

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081151